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27581	7590	06/16/2006		EXAMINER		
MEDTRON	•			GILBERT, ANDREW M		
710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924				ART UNIT	PAPER NUMBER	
				3767		
				DATE MAILED: 06/16/2006	DATE MAILED: 06/16/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

## Application No. Applicant(s) DINSMOOR ET AL.	P
Examiner Andrew M. Gilbert 3767 - The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. E tentenions of the may be examiled under the provisions of 37 CFR 1.13(g). In no event, however, may a reply be timely filled after SIX (g) MONTH'S from the mailing date of this communication. Failure to reply within that set or admisded pried for reply will by shalled, cause the application to become AMMONED (51 St. 5, 133). Any reply received by the Office later than three months after the mailing date of this communication. Failure to reply within that set or admisded pried for reply will by shalled, cause the application to become AMMONED (51 St. 5, 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patient term adjustment. See 37 CFR 1.704(b). Status 1) □ Responsive to communication(s) filed on 22 May 2006. 2a) □ This action is FINAL. 2b) □ This action is replication is in condition for allowance except for formal matters, prosecution as to the merits it closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) □ Claim(s) 1.66 is/are pending in the application. 4a) Of the above claim(s) 6.16,33-40 and 48-66 is/are withdrawn from consideration. 5) □ Claim(s) is/are allowed. 6) □ Claim(s) is/are objected to. 8) □ Claim(s) is/are objected to. 8) □ Claim(s) is/are objected to. 9) □ The specification is objected to by the Examiner. 10) □ The drawing(s) filed on 22 May 2006 is/are: a) □ accepted or b) □ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s)	
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Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/22/2006. 4) Interview Summary (PTO-413) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) Other:	

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DETAILED ACTION

Election/Restrictions

- 1. Applicant's election of Group I: Claims 1-47; Species I: Figs 3-7, 12 (Medical Device Species); and Species I: Fig 12 (Method Species) with claims 1-5, 16-28, 29-32, 41-47 readable thereon in the reply filed on 5/22/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
- Claim 16 is further withdrawn from further consideration pursuant to 37 CFR
 1.142(b) as being drawn to a nonelected Species II: Figs 8-9, 13, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 5/22/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the power source including an inductive coupling circuit to generate power from an inductive element external to the body lumen; a telemetry circuit to receive the control signal as a telemetry signal from an external controller; a magnetic circuit to sense the presence of

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an external magnetic source as the control signal; an inductive coupling circuit to generate power from an inductive element external to the body lumen and thereby drive the detachment mechanism with the generated power; a sensor, mounted to the device housing, to sense at least one condition within the body lumen; an electrical pulse generator, mounted within the device housing, to generate an electrical stimulation waveform; one or more electrodes electrically coupled to the electrical pulse generator an mounted to the device housing to deliver the electrical stimulation waveform to the body lumen must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

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Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

- 5. Claim 18 recites the limitation "the power source" in In 1. There is insufficient antecedent basis for this limitation in the claim.
- 6. Claim 19 recites the limitation "the power source" in In 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Notes

7. In reference to claim 6, the Examiner notes that the Applicant has invoked 35 U.S.C. 112 6th paragraph by using "means for" language, reciting function, and not reciting sufficient structure of the means referred to in the specification.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 9. Claims 1, 17-18, 25, 28-29, 41, 43, 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Silverstein et al, hereafter "Silverstein", (5247938). In reference to independent claim 1 and 29, Silverstein discloses the apparatus and method for

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attaching and detaching a medical device (col 1, ln 66-col 2, ln 8; Fig 1-3, 9) for placement within a body lumen of a patient, the device comprising: a device housing (48) sized for introduction into the body lumen; a fixation mechanism (col 4, lns 43-45; col 6, ln 1-15) to attach the device housing to a surface within the body lumen; a detachment mechanism (col 4, lns 43-45; col 6, lns 1-15) to selectively detach the device housing from the surface of the body lumen.

- 10. In reference to claim 17 and 41 (see col 6, lns 1-15 and the Examiner notes that a source of suction is well known to have a power source); for claim 18 (see (138)); for claim 25 and 46 (see col 4, lns 37-38); for claims 26 and 27 (see col 3, lns 43-48); for claim 43 (see col 6, lns 1-15 and the Examiner notes that when the controller of the source of suction, which is external of the body lumen, is turned off, the detachment mechanism is activate); for claim 28 and 47 (see col 3, lns 42-47).
- 11. Claims 1-3, 18-19, 24-27, 29-31, 45-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Kilcoyne et al (6689056).

The applied reference has a common invention with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another." or by an appropriate showing under 37 CFR 1.131.

In reference to independent claims 1 and 29, Kilcoyne et al discloses the apparatus and method for attaching and detaching a medical device (Figs 8-11) for

placement within a body lumen of a patient, the device comprising: a device housing (18) sized for introduction into the body lumen; a fixation mechanism (Figs 8-11) to attach the device housing to a surface within the body lumen; a detachment mechanism (col 9, lns 55-col 10, ln 4) to selectively detach the device housing from the surface of the body lumen.

In reference to claim 2 and 30 (see (124); Fig 16); for claim 3 and 31 (see col 10, lns 24-26); for claim 18 (see col 7, lns 50-53; col 7, ln 66-col 8, ln 15); for claim 19 (see col 7, ln 66-col 8, ln 15); for claim 20 (see col 9, ln 61-col 10, ln 3; col 11, ln 54-56; where the Examiner has interpreted the detector to be the bioasorbable or dissolvable material, the control signal to be psychological response by the human body to the material to begin to absorb or dissolve the attachment mechanism; thus, turning the attachment mechanism into the detachment mechanism); for claim 24-25 and 45 (see col 5, ln 63-col 6, ln 4); for claim 26-27 and 46 (see col 7, ln 17-38).

12. Claims 1-6, 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Banko (3844272). In reference to independent claims 1 and 29, Banko discloses the apparatus and method for attaching and detaching a medical device for placement within a body lumen of a patient, the device comprising: a device housing (10) sized for introduction into the body lumen; a fixation mechanism (Fig 4) to attach the device housing to a surface within the body lumen; a detachment mechanism (Fig 6) to selectively detach the device housing from the surface of the body lumen.

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13. In reference to claim 2 and 30 (see (48) and (112)); for claim 3 and 31 (see col 4, lns 53-55); for claim 4 and 32 (see 25; col 7, lns 59-60; col 7, lns 43-61); for claim 5 (see col 1, lns 30-35), for claim 6 (see col 7, lns 24-61).

Claim Rejections - 35 USC § 103

- 14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- unpatentable over Kilcoyne et al. Kilcoyne et al discloses the invention substantially as claimed except for expressly disclose a telemetry circuit, telemetry signal, magnetic circuit, external magnetic source, inductive coupling circuit, and external inductive element. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a telemetry circuit, telemetry signal, magnetic circuit, external magnetic source, inductive coupling circuit, and external inductive element because the Applicant has not disclosed that having a telemetry circuit, telemetry signal, magnetic circuit, external magnetic source, inductive coupling circuit, and external inductive element provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the detector and control signal of Kilcoyne et al because it performs substantially the same function of releasing the device from the body lumen in a user controlled manner.

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Therefore, it would have been an obvious matter of design choice to modify the control mechanism of the detachment mechanism to obtain the invention as specified in claims 21-23.

- 16. Claims 21 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al in view of Christopherson et al (6021352). Kilcoyne et al discloses the invention substantially as claimed except for expressly disclosing that the detector includes a telemetry circuit to receive the control signal as a telemetry signal from an external controller. Christopherson et al teaches that it is known to have a telemetry circuit (440; Fig 18; 20D) for the purpose of controlling the device external of the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the detector as taught by Kilcoyne et al with the telemetry circuit as taught by Christopherson et al for the purpose of controlling the device external of the body.
- 17. Claim 22 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al in view of Cimochowski et al (5967986). Kilcoyne et al discloses the invention substantially as claimed except for expressly disclosing that the detector includes a magnetic circuit to sense the presence of an external magnetic source as the control signal. Cimochowski et al teaches that it is known to have the detector includes a magnetic circuit (110; Fig 10) to sense the presence of an external magnetic source (94; Fig 10) as the control signal for the purpose of controlling the device external of the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the detector as taught by Kilcoyne with the magnetic

circuit and external magnetic source as taught by Cimochowski et al for the purpose of controlling the device external of the body.

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18. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kilcoyne et al in view of Imran et al (6535764). Kilcoyne et al discloses the invention substantially as claimed except for expressly disclosing that the detector includes an inductive coupling circuit to generate power from an inductive element external to the body lumen and thereby activate the detachment mechanism. Imran et al teaches that it is known to have the detector includes an inductive coupling circuit to generate power from an inductive element external to the body lumen and thereby activate the detachment mechanism (col 22, lns 8-30; col 23, lns 20-33) for the purpose of controlling the device external of the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the detector as taught by Kilcoyne et al with the inductive coupling circuit and inductive element external to the body lumen as taught by Imran et al for the purpose of controlling the device external of the body.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 20. Claims 1-3, 16, 18-19, 24-27, 29-31, 45-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6689056. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the US Pat No 6689056. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application. It has been held that the generic invention is anticipated by the species.
- 21. Claims 1, 18, 24-27, 29, 45-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-17, 62-87 of copending Application No. 10/833776. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending application. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application. It has been held that the generic invention is anticipated by the species.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 1-3, 18, 24-27, 29-31, 45, 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-11, 13-16, 55-58, 61-66 of copending Application No. 10/687296. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending application. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application. It has been held that the generic invention is anticipated by the species.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 1-3, 18, 19, 24-27, 29-31, 45, 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55-58, 66, 69, 71, 73 of copending Application No. 10/896533. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending application. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application. It has been held that the generic invention is anticipated by the species.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 1-3, 18, 24-31, 45, 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53

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of copending Application No. 10/835425. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending application. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application. It has been held that the generic invention is anticipated by the species.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS SUPERVISORY PATENT EXAMINER